

Opticap® XL 2 Capsule Filter with Aervent® Membrane

0.2 µm Rated
Catalogue Number: KTGRA02HH3
Lot Number: C9HN13403

Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices

ISO® 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO® 9001 Quality Systems Standard.

Non-Fiber Releasing

This product was manufactured with a PTFE membrane which meets the criteria for a "non-fiber-releasing" filter as defined in 21 CFR 210.3 (b) (6).

Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test: correlated to the *Brevundimonas diminuta* ASTM® F838 bacterial challenge test.

Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the cartridge fabrication process. In-process controls are used to assure stability of the process.

European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

Millipore, Aervent and Opticap are registered trademarks of Millipore Corporation. HydroCorr is a trademark of Millipore Corporation. ISO is a registered trademark of The International Organization for Standardization. ASTM is a registered trademark of The American Society for Testing and Materials.

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Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 CFU/cm² using ASTM® F838 methodology.

USP Bacterial Endotoxins

A sample aqueous extraction sample contains less than 0.5 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Integrity

Samples exhibited a bubble point equal to or greater than 16 psig (1100 mbar) in a 70/30% IPA/water mixture using nitrogen as the test gas at 23° C.

Samples exhibited a HydroCorr™ test value less than or equal to 0.12 mL/min at 38 psig (2620 mbar).

Thermal and Hydraulic Stress

Samples were autoclaved at 135° C and maintained integrity after a forward stress to 80 psig (5.5 bar) and a reverse stress to 60 psig (4.1 bar).

Air Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 3.5 psid (241.0 mbar) at an air flow rate of 10 SCFM (0.283 m³/min) and 0 psig (0 mbar) outlet air pressure at 23° C per 2-inch capsule.

Quality Performance Criteria

This product was designed and manufactured to meet the following specifications:

Gravimetric Extractables

The extractables level was equal to or less than 15 mg per sample after 24 hours in a 70/30% IPA/water mixture at controlled room temperature.

Toxicity

This product is non-toxic per the current USP General (Mouse) Safety Test.

Multiple Sterilization Cycles

Sample integrity was maintained after 30 autoclave cycles of 30 minutes at 135° C.

Peter Eichert
Quality Manager



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